



#28

Food and Drug Administration
Rockville MD 20857

AUG 10 1993

Re: Reality™ Female Condom (4,735,621)
Docket No. 93E-0290

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,735,621 filed by Chartex International Plc, under 35 U.S.C. § 156. The medical device claimed by the patent is Reality™ Female Condom (4,735,621), which was assigned Premarket Application (PMA) number P910064.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act.

The PMA was approved on May 7, 1993, which makes the submission of the patent term extension application on July 2, 1993, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Paul Grandinetti
Levy, Zito & Grandinetti
1910 K Street, Suite 411, N.W.
Washington, D.C. 20006-1104

RECEIVED
93 AUG 23 PM 12:55
DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS